MAY 2 0 2003

11 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K022849

1.1 Submitter's Identification:

Body Clock Health Care Ltd
108 George Lane
South Woodford
London
E18 1AD
United Kingdom
Tel: +44 (0)20 8532 9551
Fax: +44 (0)20 8532 9551

Contact: Jonathan Bash
Date Prepared: August 16th 2002

1.2 Name of Device:

Proprietary Name:
Body Clock Duo

Common or Usual Name:
Transcutaneous Electric Nerve Stimulator and
Powered Muscle Stimulator

Classification Name:
Stimulator, Nerve, Transcutaneous, For Pain Relief and
Powered Muscle Stimulator.

1.3 Predicate Device Information:

The Body Clock Duo is substantially equivalent to the FUJI TENS 804SIII (**K893874**) and the Altoona EMS 400 **(K913272)**.

Device Description:

The Body Clock Duo has two facilities, enabling it to function as both a TENS unit and as a Powered Muscle Stimulator. As a TENS unit, the Body Clock Duo transmits electrical pulses through the skin to the underlying peripheral nerves to aid in the blocking of pain signals travelling to the brain. As a Powered Muscle Stimulator, the Body Clock Duo can be used to relax muscle spasms, prevent or retard disuse atrophy, maintain or increase range of motion, increase local blood circulation, re-educate muscle and provide immediate post-surgical stimulation of calf muscle to prevent venous thrombosis.

K022249

1.4 Intended Use:

As a TENS unit, the Body Clock Duo is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

As a Powered Muscle Stimulator unit the Body Clock Duo is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. It is indicated for the following:

- Relaxation of muscle spasms;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education;
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing range of motion.

1.5 Technological Comparison to Predicate Devices:

The Body Clock Duo has basic technological characteristics that are substantially equivalent to the predicate device(s).

This unit uses dials to change the settings. It also uses shrouded patient cable connectors to comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables."

1.6 Non-clinical Testing:

- All Units are fully CE marked i.e. compliant with **EEC Directive 93/42/EEC Annex V**, classified as "Internally powered Equipment Type BF. They are intended for continuous operation."
- ISO 9002
- ISO 13488
- EN 46002
- EN 60601-1-2:1993 (**EEC Directive 89/336/EEC**)

1.7 Clinical Testing:

Not Applicable as there are no new or innovative aspects that have been introduced.

1.8 Conclusions:

The information supplied in this 510(k) illustrates that the Body Clock Duo does not pose any new questions of safety and effectiveness. The Body Clock Duo is substantially equivalent to the predicate devices and has the same intended use and same technical characteristics as them.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Mr. Jonathan Bash
Director of IT and Special Projects
Body Clock Health Care Ltd.
108 George Lane, South Woodford
London, England
United Kingdom E18 1AD

Re: K022849
Trade/Device Name: Body Clock Duo
Regulation Number: 21 CFR 882.5890, 890.5850
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief, Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, GZJ
Dated: March 20, 2003
Received: March 24, 2003

Dear Mr. Bash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8 Statement of Indications For Use

510 (k) Number (if known): K022849

Device Name: Body Clock Duo

Indications For Use:

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1. Relaxation of muscle spasms;
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3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and
Neurological Devices
510(k) Number K022849

Prescription Use X
(Per 21 CFR 801.109)